

REMARKS

Claims 1-92 are pending in the application. Claims 44, 48-57 and 65-81 have previously been withdrawn. Claims 1-43, 45-47, 58-64 and 82-92 are rejected. In response to the outstanding office action, Applicant has made amendments to claims 1-2, 4, 11, 15-16, 20, 22-23, 35, 39-40, 42-43, 46-47, 58, 62, 82, and 92. In addition, claim 41 has been withdrawn. No new claims have been added. These amendments are intended to focus the claims and to put the application in a condition for allowance. Further details regarding these amendments are outlined below.

Claim Objections due to Informalities

Claims 22 and 23 are objected to because, according to the Examiner, the phrase “electronic patent record” should be replaced with “electronic patient record.” Claim 92 is also objected to because of the improper use of a semi-colon where a colon is required. With this response to office action, claims 22, 23, and 92 have been amended in order to correct these informalities.

Claim Objections under 35 USC § 102

Claims 1-4, 6, 7, 11-16, 20, 21, 35-37, 39-43, 45-47, 58-64, 82-85 and 87-92 are rejected under 35 U.S.C. § 102(b) as being anticipated by Macrae et al., U.S. Patent No. 5,786,816 (“Macrae”). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. See, M.P.E.P. §2131.

With this response to office action, independent claim 1 has been amended to clarify that the map comprises a plurality of patient care pathways, each conforming with best practice guidelines, and each comprising a series of interlinked nodes, wherein each node in the series has a unique relationship with a respective step in the best practice workflow. Furthermore, the pathway means has been amended to clarify that it graphically indicates a suggested node to traverse next in the best practice workflow.

Independent claim 1 has also been amended to include navigation means arranged to enable the healthcare practitioner to choose the node to traverse next independently of the node

suggested by the pathway means, the navigation means further arranged to permit the healthcare practitioner to traverse a route across the map that misses out one or more nodes from the series of nodes representing a currently traversed patient care pathway. For example, Figures 4d-f of the present application illustrate a series of three interconnected nodes: an alarms node 464 which is connected to a high-risk symptoms node 466, which is in turn connected to a referral node 468. The healthcare practitioner traverses the alarms node 464 and the referral node 468, but does not traverse the high-risk symptoms node 466. The route traversed by the healthcare practitioner therefore skips, or misses out, the high-risk symptoms node 466 in this series of nodes. Accordingly, the pathway recordal portion 416 is updated to show just the alarms node 464 and the referral node 468 but not the high-risk symptoms node 466.

The graphical means in independent claim 1 has also been amended to clarify that it graphically represents in the page the route traversed by the healthcare practitioner across the map.

Turning now to the system disclosed in Macrae, the system is typical of a prior healthcare system because it is 'deterministic', i.e. it determines the path that a user must follow through a workflow, based on predefined rules and control flow. In contrast, the present invention is 'non-deterministic' because it does not take any of the decision-making away from the user. Generally speaking, the present invention provides the user with all of the information necessary for the user to make an informed decision, but ultimately the route that the user traverses through the workflow is determined solely by the user, independently of any suggestions made by the system. The amendments made to independent claim 1 are intended to clarify this difference.

Specifically, Macrae describes a GUI for graphically representing medical healthcare plans as a plurality of nodes (see Abstract). The system enables a generic healthcare template to be adapted and assigned to patients according to the specific needs of that patient (see for example col. 5, lines 38-41). Before constructing the healthcare plan for a patient, the user must first decide on the steps to be carried out, and the order in which those steps will be carried out (see for example col. 7 lines 24-26, "*before a user can create a template, treatment work flow must be defined; that is the order in which treatment activities are to be carried out for a given condition*"; column 7, lines 61-63: "*When building a template, nodes are positioned in the chronological order in which they are to be carried out or executed*", and column 7 line 64-col.8

line 3: “*Template creation involves...deciding on the circumstances and order in which each template step is executed during treatment*”).

In Macrae, the route taken through the workflow is governed by Flow Control Nodes. As described in column 13, lines 47-51 of Macrae, “[e]ach Flow Control Node contains a set of rules that determine which Order nodes will be executed in the next step of the template. A user defines the rules by creating simple expressions that reference the results of completed orders or other variables in the template”. As the user progresses through the template, the user is automatically taken to a next node on the basis of the information entered at a previous node, in dependence on predefined rules: col. 19, lines 12-17: “*The GUI, according to the present invention, automatically determines the next step in the care flow based on the results of the strep test even though the vitals were not completed*”; col. 20, lines 29-34: “*Enter the results of the strep test...and click the Done button...the plan branches down the strep path*”.

In his analysis of Macrae, the Examiner noted that Macrae suggests a next step within the workflow (see column 7 lines 54-60: “*During patient charting, the Flow Control node suggests the next step to the healthcare provider based on the rules and the results entered in Result nodes. A typical rule in a Flow Control node looks like this: If(Rel:CBC:Hct:Val<=25)GOTO Transfusion at 5%*”). As discussed above, independent claim 1 has been amended to clarify the function of the pathway means of the present invention. Specifically, amended claim 1 now includes the feature that the pathway means **graphically indicates** a suggested node to traverse next. There is no disclosure in Macrae of the GUI *graphically indicating* a suggested next node as shown, for example, in Figure 6a of the present application, and now recited in amended claim 1.

Macrae does contemplate probability values associated with each path to determine the most probable path through the plan (see column 20, lines 25-27: “*The probability values associated with each rule determine the most probable path through the plan. In this example, the Virus path is the most probable*”). The most probable paths in Macrae are **predefined** when the plans are created. Consequently, this disclosure does not anticipate the function of the pathway means as defined in amended claim 1 because displaying a **predetermined** most probable path is not equivalent to suggesting a next step **based on data entered by the healthcare practitioner** during progression through the workflow, as required by claim 1.

The inclusion of the **navigation means** in amended independent claim 1 further clarifies the difference between the present invention and Macrae. In amended claim 1, the navigation means allows **the healthcare practitioner to choose the next node** to traverse independently of the node suggested by the pathway means. From the code used in the rules in Macrae (e.g. the 'IF' and 'GOTO' in *If(Rel:CBC:Hct:Val<=25)GOTO Transfusion at 5%*) it is evident that when Macrae describes suggesting a next step (col. 7 lines 54-60), what actually happens is that the workflow automatically progresses to that suggested step according to the predefined rules at the Flow Control Node and on the basis of the previously entered results. This is confirmed at column 18, line 50-53 of Macrae: *"When all of the order results specified in a rule are entered, the rule is evaluated. If the rule is satisfied, the rule will become active and take the plan down the corresponding path"*. This is also confirmed at col. 19, lines 12-17: *"The GUI, according to the present invention, automatically determines the next step in the care flow based on the results of the strep test even though the vitals were not completed"*; and at col. 20, lines 29-34: *"Enter the results of the strep test...and click the Done button...the plan branches down the strep path"*. There is no disclosure in Macrae of the GUI **graphically indicating a suggested next node**, and then the user **choosing** the next node independently of that suggestion.

Macrae also describes the possibility of overriding the predetermined rules to enable the user to choose any branch at a flow control node. At column 19, lines 52-63 of Macrae, it is described that there are two possible ways of manually executing a plan: option (a) the user may force the plan to branch down a specific path, regardless of the results at the previous node, by manually executing the rule associated with that path; or option (b) the user may reexecute a step in the plan, for example, if treatment has gone down one path and a user needs to back up the plan to go down another path. However, this disclosure in Macrae still does not describe **graphically indicating a suggested next node**, and then enabling the user to **choose** the next node **independently** of that suggestion as required by amended claim 1. In option (a), if the user were to force the plan down a branch, then there is no prior graphical indication of a suggested next node. In option (b), even if one were to stretch the interpretation of *graphically indicating* a suggested next node to cover the case of the plan automatically progressing to that node, then there would be no disclosure of the GUI enabling **the user to choose** the next node **independently** of that suggestion because the plan would have automatically advanced to the

next node, i.e. the next node has been determined automatically.

To further clarify the differences between Macrae and the present invention, amended claim 1 recites the feature of the pathway means being arranged to permit the healthcare practitioner to traverse a **route** across the map that **misses out one or more nodes from the series of nodes representing a currently traversed patient care pathway**. There is no disclosure in Macrae of the user being able to traverse a route through the plan that *misses out* one or more nodes in a series of interlinked nodes. Such a feature would run contrary to the teaching of Macrae, which as already mentioned above, is concerned with **predefining** the order in which the various steps of the plan are to be carried out (the Examiner's attention is once again directed to the following parts of Macrae: col. 7 lines 24-26, *"before a user can create a template, treatment work flow must be defined; that is the order in which treatment activities are to be carried out for a given condition"*; column 7, lines 61-63: *"When building a template, nodes are positioned in the chronological order in which they are to be carried out or executed"*, and column 7 line 64-col.8 line 3: *"Template creation involves...deciding on the circumstances and order in which each template step is executed during treatment"*). While the user in Macrae is able to force the plan to branch down a given path at a branch node, this, however, is not equivalent to missing out one or more nodes from a series of nodes representing a currently traversed pathway. Whichever path the user in Macrae follows, he must still execute every node in the series of interlinked nodes representing that path. He cannot skip or miss out a node in the series because he has previously defined the order in which the steps are to be carried out or executed. Advantageously, with the present invention, the possible routes through the map are limitless. In contrast, Macrae teaches a limited number of predefined paths (see Macrae col. 6 lines 46-48: *"Cost view 22 also shows every possible path through the template and lists the cost of each path"*).

Because Macrae fails to disclose each and every element of Applicant's invention as recited in independent claim 1, Applicant respectfully submits that the reference does not anticipate claim 1. Therefore, Applicant respectfully requests that the rejection of independent claim 1 under 35 U.S.C. § 102 be withdrawn.

Claims 2-43 and 45 depend from independent claim 1, which is allowable for at least the reasons stated above. As such, these claims are allowable with their independent base claim. M.P.E.P. §2143.03.

Independent claim 46 has been amended similar to independent claim 1 discussed in detail above. Thus, for at least the reasons stated above in reference to the rejection of independent claim 1, Macrae also fails to disclose each and every element of Applicant's invention as recited in independent claim 46. As a result, Applicant respectfully submits that the reference does not anticipate independent claim 46, and requests that the rejection of claim 46 under 35 U.S.C. § 102 be withdrawn.

Independent claim 47 has also been amended similar to independent claim 1 discussed in detail above. Thus, for at least the reasons stated above in reference to the rejection of independent claim 1, Macrae also fails to disclose each and every element of Applicant's invention as recited in independent claim 47. As a result, Applicant respectfully submits that the reference does not anticipate independent claim 47, and requests that the rejection of claim 47 under 35 U.S.C. § 102 be withdrawn.

With this response to office action, independent claim 58 has been amended to clarify that the map comprises a plurality of patient care pathways, each conforming with best practice guidelines, and each comprising a series of interlinked nodes, wherein each node in the series has a unique relationship with a respective step in the best practice workflow. Additionally, amended claim 58 is now directed to a plurality of GUIs, each having access to a respective centrally-stored version of a clinical workflow, and each arranged to update the respective centrally-stored version of the workflow when the nodes on the page are edited by the healthcare practitioner via the GUI.

Thus, amended claim 58 relates to a plurality of GUIs, which are each arranged to display a respective version of a clinical workflow. Each GUI has editing means allowing the nodes to be edited by the healthcare practitioner, and updating means arranged to update the respective centrally-stored version of the stored clinical best practice workflow with any corresponding changes made to the nodes by the healthcare practitioner. Dissimilarly, Macrae describes stand-alone systems arranged to access locally-stored templates (see for example Macrae col.5 line 41 to col.6 line 9). As such, Macrae does not describe centrally-stored workflows as now required

by claim 58.

Macrae also describes a server-client arrangement (see Macrae from col. 29 line 31 to col. 35, line 23, and Figures 26-30). However, in this arrangement, the clients all access the *same version* of a template. Macrae describes a “Lock and Unlock Method” for locking the template whilst it is edited by one of the clients (see Macrae col. 33, lines 55 to 64: “*Clients that wish to make changes to a template will need to obtain a lock on a template instance. The Lock method 373 allows clients to obtain a lock or indicates the template is currently locked by another client. Clients must obtain a lock before making changes to a template. Once the changes are complete, they must call the Unlock method 374 to free the template instance so that other clients may make changes. Clients that only need to view a template (without making changes) need not obtain a lock on the template...*”). Accordingly, Macrae does not describe a plurality of GUIs capable of editing and updating respective *centrally-stored versions* of a workflow as required by amended claim 58, because the plurality of GUIs in Macrae all access the *same version* of the template. Macrae teaches away from having multiple centrally-stored versions of the workflow, in favour instead of having the lock and unlock system to allow multiple users to edit the same template, one at a time. Advantageously, with the present invention, multiple users can edit their respective centrally-stored versions of the workflow independently of one another. This means that users can edit the workflow simultaneously, making the GUIs more flexible. Furthermore, by allowing individual users, or groups of users, to edit their own centrally-stored versions of the workflow, changes made to the workflow may only be visible by the respective user or group of users of that particular centrally-stored version. This enables local variations of the workflow to be created to accommodate, for example, different courses of treatment favoured by different hospitals.

Because Macrae fails to disclose a plurality of GUIs arranged to edit and update respective centrally-stored versions of a workflow as required by amended claim 58, and because the lock and unlock method teaches away from the present invention, Macrae fails to disclose each and every element of Applicant’s invention as recited in independent claim 58. As a result, Applicant respectfully submits that the reference does not anticipate independent claim 58, and requests that the rejection of claim 58 under 35 U.S.C. § 102 be withdrawn.

Claims 59-64 depend from independent claim 58, which is allowable for at least the

reasons stated above. As such, these claims are allowable with their independent base claim. M.P.E.P. §2143.03.

Independent claim 82 has been amended similar to independent claim 1 discussed in detail above. Thus, for at least the reasons stated above in reference to the rejection of independent claim 1, Macrae also fails to disclose each and every element of Applicant's invention as recited in independent claim 82. Independent claim 82 is additionally novel over Macrae because Macrae does not describe *automatically generating a graphical representation of the hierarchical clinical best practice workflow from the content recorded in the database* as required by claim 82. The graphical representation in Macrae is not created *automatically* as required by claim 82, but rather manually by the user positioning nodes on the page (as described, for example, at column 7, lines 61-63 and column 9, lines 3-6). Furthermore, claim 82 requires that the content is created first and the graphical representation generated subsequently from this content. In Macrae, the order is reversed: i.e. the graphical representation is generated first, and the content added subsequently. For at least the foregoing reasons, Applicant respectfully submits that the reference does not anticipate independent claim 82, and requests that the rejection of claim 82 under 35 U.S.C. § 102 be withdrawn.

Claims 83-91 depend from independent claim 82, which is allowable for at least the reasons stated above. As such, these claims are allowable with their independent base claim. M.P.E.P. §2143.03.

Independent claim 92 has also been amended similar to independent claim 1 discussed in detail above. Thus, for at least the reasons stated above in reference to the rejection of independent claim 1, Macrae also fails to disclose each and every element of Applicant's invention as recited in independent claim 92. As a result, Applicant respectfully submits that the reference does not anticipate independent claim 92, and requests that the rejection of claim 92 under 35 U.S.C. § 102 be withdrawn.

Claim Objections under 35 USC § 103

Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Macrae *supra*. Claims 8-10, 28-34 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Macrae *supra* and DeBusk et al., U.S. Patent No. 6,314,556 ("DeBusk"). Claims 17-19 are

rejected under 35 U.S.C. § 103(a) as being unpatentable over Macrae *supra* and Balint et al., U.S. Patent No. 5,542,024 (“Balint”). Claims 22-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Macrae *supra* and Campbell et al., U.S. Patent No. 6,047,259 (“Campbell”). Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Macrae *supra* and Greenberg et al., U.S. Patent Pub. No. 2004/0039602 (“Greenberg”). Claim 86 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Macrae *supra* and Huyn et al., U.S. Patent Pub. No. 2002/0035486 (“Huyn”). Applicant respectfully requests withdrawal of these rejections and allowance of these claims.

The pending claims are not-obvious over the Macrae system. Whereas Macrae is concerned with predefining rules and control flow, the present invention is concerned with allowing the user to navigate his or her own route through a map without being restricted by rules or predefined control flow. With the present invention, the user chooses his or her own route (which is recorded) through the workflow as he or she traverses the workflow. The user is not required to follow a path from start to finish or follow a predefined order or chronology of steps as required by Macrae.

Furthermore, with the advantages provided by the present invention, the user does not have to build the workflow or define the order of steps before he or she can traverse the workflow as required by Macrae. This increases the healthcare practitioner’s efficiency because he or she can concentrate on diagnosing and treating patients rather than first having to construct patient care plans by customising templates as required by Macrae. Furthermore, by permitting the user to miss out nodes from a series of nodes, the same map can be used for various patients without having first having to customise it.

Claims 5, 8-10, 17-19, 22-34, and 38 depend from independent claim 1, which is allowable for at least the reasons stated above. Claim 86 depends from independent claim 82, which is also allowable for at least the reasons stated above. As such, these claims are allowable with their independent base claims. M.P.E.P. §2143.03.

Conclusion

In light of the above amendments and arguments Applicant asserts that the present invention, as claimed, is allowable and requests favourable consideration by the Examiner.

In the event a telephone conference would expedite the prosecution of this application, the Examiner may reach the undersigned at 612-607-7302. If any additional fees are due in connection with this Amendment and Response, the Commissioner is hereby authorized to charge such fees, including extension of time fees, to Deposit Account No. 50-1901 (Ref. No. 22557-3001).

Respectfully submitted,

By  _____

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